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## SECTION 5

## 510(K) SUMMARY

**Submitter:**

Devon Medical Products, Inc.

**Contact Person:**

Ruth Wu, COO
1100 First Avenue, Suite 202
King of Prussia, PA 19406
Phone: 866.446.0092
Fax: 484.636.0211

**Common Classification & Proprietary Names:**

Common Names: Negative Pressure Wound Therapy System
Proprietary Name: extriCARE 2400

**Date Prepared:**

August 29, 2011

**Classification**

The classification name, 21 CFR Part and Paragraph number, product code and classification of the extriCARE 2400:

| FDA | Classification | Product Code | Class |
|---|---|---|---|
| 21 CFR 878.4780 | Powered Suction Pump | OMP | II |

**Predicate Devices:**

The extriCARE 2400 Negative Pressure Wound Therapy System is substantially equivalent to the following.

| Predicate Device | Manufacturer | 510(k)# |
|---|---|---|
| NPD 1000 | Kalypto Medical | K080275 |
| MoblVAC W.C. | Ohio Medical | K081185 |
| Renasys Gauze Dressing Kit | Smith & Nephew | K110647 |

**Device Description**

The system consists of a vacuum pump, canister, and tubing. In operation, the device is attached via the tubing to a Negative Pressure Wound bandage. Maximum pressure and mode selection are digitally programmable. The extriCARE pump can be sold alone or as a part of the extriCARE 2400 system with extriCARE bandages. The extriCARE bandages are an all-in-one wound dressing, with no wound packing required.

**Intended Use:**

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The extriCARE 2400 Negative Pressure Wound Therapy System is a portable, battery powered pump intended to generate negative pressure or suction to remove wound exudates, infectious material, and tissue debris from the wound bed which may promote wound healing.

**Technological Characteristics:**

The manufacturer believes that the technological characteristic of the extriCARE 2400 are substantially similar to those of the predicate devices. The extriCARE 2400 has very similar components to its predicate devices and very similar principles of operation. The device consists of an electrically generated source of vacuum, a canister. Like the predicates, vacuum, is applied for a specified period of time and intensity, according to the physician's prescription.

**Performance Testing**

To verify that the device design met it's functional and performance requirements, representative samples of the device underwent function and mechanical testing, EMC testing in accordance with IEC 60601-1-2 and electrical safety testing in accordance with UL 60601-1.

| Function Performance Tests | |
|---|---|
| PQ-01 | extriCARE 2400 Vacuum Pressure Calibration |
| PQ-02 | Comparison on SE for Vacuum Pressure Calibration |
| PQ-03 | Treat Time verification on Intermittent Mode for extriCARE 2400 |
| PQ-04 | Flow Rate Performance on for extriCARE 2400 |
| PQ-05 | Alarm Verification for extriCARE 2400 |
| PQ-06 | Battery Verification for extriCARE 2400 |
| PQ-07 | Exudate Removal test on extriCARE 2400 and extriCARE bandage |
| PQ-08 | Peel strength test on extriCARE Bandage T-ZG-027 |
| PQ-09 | Shear Adhesion test on extriCARE Bandage T-ZG-065 |
| PQ-10 | Leakage test on extriCARE Bandage |

**Biocompatibility**

The extriCARE 2400 system consists of both the pump and the bandage. While the pump has no direct body contact when used as indicated, the bandage does have direct body contact. Per ISO-10993 B-prolonged contact(24h – 30 days) requirements, the bandage samples were tested for the following items and all tests were successfully passed.

| | | Date | Protocol # | Result Summary |
|---|---|---|---|---|
| Test 1 | ISO Guinea Pig Maximization Sensitization Test (GLP) | Oct 8, 2010 | Wuxi AppTec 900850-23 | The test article did not elicit sensitization response. |
| Test 2 | Cytotoxicity - MEM | Oct 29, 2010 | Nelson | Non-cytotoxic |

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| | | | | |
|---|---|---|---|---|
| | Elution without silver (ISO) | | 201003532 Rev 01 | |
| Test 3 | Cytotoxicity – MEM Elution with silver (ISO) | Oct 21, 2010 | Nelson 201003441 Rev 01 | Non-cytotoxic |
| Test 4 | Intracutaneous Irritation | Nov 11, 2010 | NLI# 550001 | Non-irritant |

**Statement of Substantial Equivalence**

The extriCARE 2400 system is substantially equivalent in technology, function, operating parameters, and intended use to predicate devices that are currently commercially available and in distribution, and does not raise any new questions of safety or effectiveness.

**Conclusions**

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, Devon Medical Products, believes that the extriCARE 2400, is safe and effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Devon Medical Products, Inc.
% Ms. Ruth Wu, COO
1100 First Avenue, Suite 202
King of Prussia, Pennsylvania 19406

FEB 10 2012

Re: K110078
Trade/Device Name: extriCARE 2400
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 18, 2012
Received: January 31, 2012

Dear Ms. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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## SECTION 4

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: extriCARE 2400

The extriCARE 2400 Negative Pressure Wound Therapy Pump System is a portable, battery powered pump intended to generate negative pressure or suction to remove wound exudates, infectious material, and tissue debris from the wound bed which may promote wound healing.

Prescription Use ___X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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